

EXHIBIT I

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN COLOR INTRAORAL SCANNERS
AND RELATED HARDWARE AND SOFTWARE**

INV. NO. 337-TA-1091

**INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND
RECOMMENDED DETERMINATION ON REMEDY AND BOND**

Administrative Law Judge Clark S. Cheney

(March 1, 2019)

Appearances:

For the Complainant Align Technology, Inc.:

Blair M. Jacobs, Esq., Christina A. Ondrick, Esq., John S. Holley, Esq., and Mark Consilvio, Esq. of Paul Hastings LLP of Washington, DC.

Thomas A. Counts, Esq. of Paul Hastings LLP of San Francisco, CA.

Raymond W. Stockstill, Esq. of Paul Hastings LLP of Costa Mesa, CA.

Joshua M. Bennett, Esq. of Paul Hastings LLP of New York, NY.

For the Respondents 3Shape A/S, 3Shape Trios A/S, and 3Shape Inc.:

Goutam Patnaik, Esq., Tuhin Ganguly, Esq., David J. Shaw, Esq. of Pepper Hamilton LLP of Washington, DC.

William D. Belanger, Esq., Gregory D. Len, Esq., Frank D. Liu, Esq., Brittanee L. Friedman, Esq., L. Andrew Tseng, Esq. of Pepper Hamilton LLP of Boston, MA.

Charles F. Koch, Esq. of Pepper Hamilton LLP of Redwood City, CA.

S. Lloyd Smith, Esq., Kimberly E. Coghill, Esq., Kyle Tsui, Esq. of Buchanan Ingersoll & Rooney PC of Alexandria, VA.

Philip L. Hirschhorn, Esq. of Buchanan Ingersoll & Rooney PC of New York, NY.

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Pursuant to the Notice of Investigation, 82 Fed. Reg. 60418 (Dec. 20, 2017), this is the final Initial Determination in the matter of *Certain Color Intraoral Scanners and Related Hardware and Software*, Investigation No. 337-TA-1091. 19 C.F.R. §§ 210.10(b), 210.42(a)(1)(i).

For the reasons stated herein, I have determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software alleged to infringe U.S. Patent No. 8,363,228 (“the ’228 patent”); U.S. Patent No. 8,451,456 (“the ’456 patent”); U.S. Patent No. 8,675,207 (“the ’207 patent”); U.S. Patent No. 9,101,433 (“the ’433 patent”). I have further determined that the investigation should be terminated with respect to articles alleged to infringe U.S. Patent No. 6,948,931 (“the ’931 patent”); and U.S. Patent No. 6,685,470 (“the ’470 patent”), without a finding of violation.

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I. INTRODUCTION

A. Procedural History

On November 14, 2017, complainant Align Technology, Inc. of San Jose, California (“Align”) filed a complaint alleging violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain color intraoral scanners and related hardware and software by reason of infringement of one or more of U.S. Patent No. 8,363,228 (“the ’228 patent”); U.S. Patent No. 8,451,456 (“the ’456 patent”); U.S. Patent No. 8,675,207 (“the ’207 patent”); U.S. Patent No. 9,101,433 (“the ’433 patent”); U.S. Patent No. 6,948,931 (“the ’931 patent”); and U.S. Patent No. 6,685,470 (“the ’470 patent”). 82 Fed. Reg. 60418 (Dec. 20, 2017).

On December 20, 2017, the Commission instituted this investigation to determine:

whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software by reason of infringement of one or more of claims 1, 2, 4, 5, 7, 18, 20, 21, and 26 of the ’228 patent; claims 1–8 and 15–18 of the ’456 patent; claims 1, 2, 4, and 15–21 of the ’207 patent; claims 1, 4, 7, 10, 12, and 14 of the ’433 patent; and claims 1–12 of the ’931 patent; and claims 1–12 of the ’470 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337.

Id.

The named respondents were 3Shape A/S of Copenhagen, Denmark; and 3Shape Inc. of Warren, New Jersey. *See id.* at 60419. On March 15, 2018, I granted Align’s unopposed motion to amend the complaint and notice of investigation to add 3Shape Trios A/S of Copenhagen, Denmark as an additional respondent in this investigation. Order No. 11; *see also* Notice of a Commission Determination not to Review an Initial Determination Granting a Motion for Leave to Amend the Complaint and Notice of Investigation to Add Respondent (Mar. 26, 2018) (EDIS

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Doc. ID 640017). Throughout the investigation, all parties have referred to the three 3Shape entities collectively as “3Shape,” and I follow that convention in this determination.

The Commission investigative staff is not a party to this investigation.

On, May 18, 2018, I denied 3Shape’s motion for summary determination and termination of the investigation based on a forum selection clause in a Scanner Agreement between Align and 3Shape Trios A/S. Order No. 23. On July 10, 2018, I granted Align’s unopposed motion for termination of the investigation with respect to claim 7 of the ’456 patent; claims 1-4, 7, and 10 of the ’433 patent; claims 4-12 of the ’470 patent; and claims 4-12 of the ’931 patent. Order No. 27; *see also* Notice of a Comm’n Det. not to Review an Initial Det. Granting a Mot. for Partial Term. of the Inv. Based on Withdrawal of Certain Claims (Aug. 7, 2018) (EDIS Doc. ID 652179). On July 11, 2018, I denied 3Shape’s motion for summary determination of no violation with respect to the entity 3Shape Inc. Order No. 28. On September 6, 2018, I denied 3Shape’s motion to terminate the investigation with respect to the ’470 and ’931 patents on the basis that those patents would expire six days before the May 20, 2019, target date then in effect for this investigation. Order No. 34.

I convened an evidentiary hearing on September 17-21, 2018, to determine whether section 337 has been violated by reason of the importation into the United States, the sale for importation, or the sale within the United States after importation of allegedly infringing color intraoral scanners and related hardware and software. Following the close of the evidentiary hearing, a lapse in government appropriations from December 22, 2018, through January 25, 2019, caused the Commission to temporarily cease regular operations, which precluded completion of this initial determination. On January 29, 2019, I issued an initial determination extending the target date in

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this investigation to July 1, 2019, which correspondingly extended the deadline for certifying the record and a final initial determination on violation to March 1, 2019. Order No. 39.

B. The Parties

1. Complainant Align Technology, Inc.

Align is a publicly-traded corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 2820 Orchard Parkway, San Jose, California 95134. 2d Am. Compl. at ¶ 13. Align is the owner by assignment of the asserted patents in this investigation. *See* JX-0001 at Cover; JX-0002 at Cover; JX-0039 (assignment record); JX-0040 (assignment record); JX-0041 (assignment record).

2. The 3Shape Respondents

3Shape A/S, 3Shape Trios A/S, and 3Shape Inc. are “sister” corporations that are wholly-owned subsidiaries of 3Shape Holdings A/S. *See* RPB at 13.

a) 3Shape Trios A/S

3Shape Trios A/S is a Danish corporation with its principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark. 3Shape Trios A/S develops and sells the accused Trios scanners, including the Trios application software and ScanSuite Trios software included on those scanners. *See* RPB at 13.

b) 3Shape A/S

3Shape A/S is a Danish corporation with its principal place of business at Holmens Kanal 7, 1060 Copenhagen K, Denmark. 3Shape represents that 3Shape A/S develops and sells certain “lab scanner” products not accused in this investigation. 3Shape A/S also develops, sells, and licenses 3Shape’s accused Dental System and Ortho System software. *See* RPB at 13.

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c) 3Shape Inc.

3Shape Inc. is a Delaware corporation with a principal place of business at 10 Independence Boulevard, Suite 150, Warren, New Jersey 07059. 3Shape represents that “3Shape Inc. is 3Shape’s regional support entity for North America. It supports 3Shape’s U.S. distributors, or ‘resellers’ by providing marketing and after-sales support and training, including administering 3Shape’s warranty, repair, and replacement program.” RPB at 13.

C. The Asserted Patents

Align asserts two categories of patents in this investigation: (1) the color scanner patents and (2) the gingival deformation patents.

1. The Color Scanner Patents

The parties refer to the ’228, ’456, ’207, and ’433 patents collectively as “the color scanner patents.”

United States Patent Number 8,363,228, entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on January 29, 2013. JX-0003 at cover page. The patent issued from Application Number 13/333,351, filed on December 21, 2011, and claims priority to provision application No. 60/580,109, filed on June 17, 2004, and provisional application No. 60/580,108 filed on June 17, 2004. *Id.* The patent, on its face, is assigned to Cadent Ltd. *Id.* Align acquired ownership of the patent through assignment. *See* JX-0039.

United States Patent Number 8,451,456 entitled “Method and Apparatus for Colour Imaging a Three-Dimensional Structure,” issued to Noam Babyoff on May 28, 2013. JX-0004 at cover page. The patent issued from Application Number 13/620,159, filed on September 14, 2012, and claims priority to provisional application No. 60/580,109, filed on June 17, 2004, and

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See Tr. at 677:6-678:2. Align makes no attempt to explain why its expert could not calculate a price differential based on a comparison of the sale price charged to end-users of each scanner. Indeed, the record indicates that one reseller—Patterson Dental—sells both iTero and Trios scanners, making the absence of such a comparison particularly suspect. *See* Tr. at 421:25-422:5; JX-0192 at ¶ 2. I also note that in other investigations, differences in distribution models have not prevented experts from conducting price comparisons based on retail prices. *See Certain Dental Ceramics, Products Thereof, and Methods of Making the Same*, Inv. No. 337-TA-1050, Initial Determination on Violation of Section 337 and Recommended Determination on Remedy and Bond at 107-110 (Aug. 28, 2018) (summarizing the parties' competing price differential calculations where complainants and respondents used different distribution models).

Align has not demonstrated that it would impractical to calculate a bond rate based on the retail price differential between the iTero and Trios scanners. Rather, the evidence suggests that Align simply did not attempt to calculate a price differential, even though the record reveals at least one distributor that sells both products to end users. *See* Tr. at 421:25-422:5; JX-0192 at ¶ 2. Because Align bears the burden to support the 100% bond rate it has proposed, but has not carried that burden, I recommend that the Commission enter a bond rate of 0% should it find a violation.

IX. INITIAL DETERMINATION

Based on the foregoing, I have determined that no violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain color intraoral scanners and related hardware and software with respect to U.S. Patent No. 8,363,228; U.S. Patent No. 8,451,456; U.S. Patent No. 8,675,207; or U.S. Patent No. 9,101,433. I have further determined

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the investigation should be terminated with respect to articles alleged to infringe U.S. Patent No. 6,948,931 and U.S. Patent No. 6,685,470 without a finding of violation.

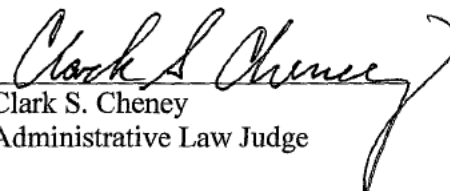
I hereby certify to the Commission this Initial Determination and the Recommended Determination.

The Secretary shall serve the confidential version of this Initial Determination upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation. A public version will be served at a later date upon all parties of record.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

Within seven days of the date of this document, each party shall submit a statement to Cheney337@ustic.gov stating whether or not it seeks to have any portion of this document redacted from the public version. Any party seeking to have any portion of this document redacted from the public version thereof shall attach a copy of this document with red brackets indicating any portion asserted to contain confidential business information.¹⁷ The parties' submissions concerning the public version of this document should not be filed with the Commission Secretary.

SO ORDERED.


Clark S. Cheney
Administrative Law Judge

¹⁷ If the parties submit excessive redactions, they may be required to provide an additional written statement, supported by declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in Commission Rule 201.6(a). 19 C.F.R. § 201.6(a).

**CERTAIN COLOR INTRAORAL SCANNERS AND
RELATED HARDWARE AND SOFTWARE**

Inv. No. 337-TA-1091

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND** has been served by hand upon the following parties as indicated, on **July 15, 2019**



Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainant Align Technology, Inc.:

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- ☐ Via Hand Delivery
☒ Via Express Delivery
☐ Via First Class Mail
☐ Other: _____

On Behalf of Respondents 3Shape A/S and 3Shape, Inc.:

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☒ Via Express Delivery
☐ Via First Class Mail
☐ Other: _____